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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,636	10/26/2001	Jose de Jesus de la Fuente	67686/00-602	1974

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EXAMINER
MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
1645	6

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/002,636	Applicant(s) DE LA FUENTE ET AL.
	Examiner N. M. Minnifield	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 3 sheets
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-8 are now pending in the present application.

Sequence Requirements

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s): the specification contains nucleotide sequences, but has no sequence identifier (i.e. SEQ ID NO) see pages 8 and 15 for example.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the office action set forth below. Failure to fully comply with ***both*** these requirements in the time period set forth in this office action will be held non-responsive.

3. The use of the trademark (see pages 11 and 19 for example) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine comprising a pharmaceutically acceptable carrier or diluent and a recombinant MSP1a antigen or recombinant MSP1a antigen in combination with antigen preparation derived from *A. marginale* infected culture tick IDE8 cells and methods of inducing an immune response in a ruminate to provide immune protection comprising administering the vaccine, does not reasonably provide enablement for a vaccine comprising a subunit of recombinant MSP1a and methods of inducing an immune response in a ruminate to provide immune protection comprising administering the subunit vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification sets forth examples of the vaccine composition (MSP1a alone or cells and MSP1a as described above) and methods of using (see page 10). The specification is not enabled for a vaccine comprising the subunit of the recombinant MSP1a, or for methods of inducing immune protection. The

specification does not teach one of ordinary skill in the art how to obtain or prepare the subunits of the recombinant MSP1a. How much of the MPS1a is needed to constitute a subunit such that vaccine protection is achieved and what portions of the MSP1a are needed? Where are the epitopes on the MSP1a?

It is noted that the art does not teach one how to obtain an appropriate subunit of MSP1a useful as a vaccine. Problems to be overcome in the development of molecular vaccines are antigenic variation, that occurs in persistently infected cattle, and presentation of the antigen to the bovine immune system to achieve optimal protective responses (Kocan et al, p. 506). Palmer et al, 1995 teach that the epitopes responsible for inducing protective immunity following infection or killed whole organism immunization are unknown and are not easily identified with these complex immunogens (p. 235). Palmer et al also indicates that protective immunity can be achieved with native or recombinant MSP1 and other MSPs. "Although this efficacy supports the outer membrane polypeptide approach and indicates that subunit induced immunity is achievable, none of the immunogens have been rigorously optimized to determine if the level of protection is sufficient for protection in the field." (p. 236). Further, Palmer et al states that immunization with either recombinant MSP1a or MSP1a/b provides inconsistent protection with a minority being completely protected from disease (p. 237). Munderloh et al teach that subunit vaccines provide only partial protection against challenges. Palmer et al, 1989 teaches that the contribution of each MSP1 polypeptide to the protective immunity is unknown. Both polypeptides have surface exposed epitopes and are immunogenic when presented in the MSP1 complex (p. 3668). Therefore a subunit

of the MSP1a as a vaccine would be difficult since it is not clear what contribution each of the larger polypeptides make to the protective immunity.

In view of the state of the prior art on subunit vaccines against anaplasmosis, there would be undue experimentation required for the skilled artisan to make and use a vaccine comprising a subunit of recombinant MSP1a.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire et al, 1994 or McGarey et al, 1994 (Infection and Immunity; 62/10:4594-4601).

McGuire et al discloses that the MSP1 is a heterodimer of MSP1a and MSP1b, that the MSP1a is prepared recombinantly (p. 465) as well as the need for improved control procedures including more effective vaccines.

McGarey et al discloses that the A. marginale MSP1 is composed of a two subunits MSP1a and MSP1b and that these polypeptides have been made recombinantly (abstract; materials and methods). McGarey et al discloses the

recombinant MSP1a antigen in a pharmaceutically acceptable carrier (i.e. adjuvant) see p. 4595. It is noted that the recitation of "vaccine" is viewed as intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The prior art vaccine composition appears to be the same or similar to that claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine composition with the vaccine composition of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed vaccine composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Barbet et al, 1999 or Barbet et al (EP 196290).

Barbet et al, 1999 disclose a composition comprising MSP1a in PBS (materials and methods), and that the proteins have potential value in diagnostic assays and vaccine value (p. 103; p. 106). It is noted that "recombinant" is viewed as a process limitation.

Barbet et al (EP 196290) disclose a substantially pure antigenic surface protein from *A. marginale* having a molecular weight of 105 kD (abstract; pp. 1-2). Barbet et al disclose that the protein can be used as a vaccine (p. 4; claims; p. 15). The vaccine can contain pharmaceutically acceptable carriers or diluents (p. 5). Barbet et al discloses immunization studies (i.e. methods for inducing an immune response in a ruminate to provide immune protection) and that the Am105 (i.e. MSP1a) is capable of inducing significant protection against challenge with *A. marginale* (pp. 22-24).

The prior art vaccine composition and methods appear to be the same or similar to that claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine composition and methods with the vaccine composition and methods of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed vaccine composition and methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Allred et al, 1990 in light of McGarey et al, 1994 (Infection and Immunity; 62/10:4587-4593).

Allred et al discloses AmF105 subunit of MSP1 (abstract). Allred et al discloses that the surface protein should aid in dissection of the immune response to these pathogens (rickettisa), their potential mechanisms of immune invasion, and the development of vaccines (p. 3324).

It is noted that McGarey et al discloses that the MSP1a has a molecular weight of 105 kD (abstract).

The prior art vaccine composition appears to be the same or similar to that claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine composition with the vaccine composition of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed vaccine composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire et al (5549898) in light of McGarey et al, 1994 (Infection and Immunity; 62/10:4587-4593).

McGuire et al discloses a purified antigenic surface protein of *A. marginale* and that the antigen is useful as a vaccine component for protecting mammals against infection by *A. marginale* (abstract; col. 1; col. 6; col. 17; claims). This protein has a molecular weight of 105 kD (figures; col. 2; col. 4). The protein has been produced by recombinant DNA techniques (cols. 4-8). McGuire et al disclose that the vaccine also contains adjuvants or any other suitable pharmaceutically acceptable carrier or diluent (col. 8).

It is noted that McGarey et al discloses that the MSP1a has a molecular weight of 105 kD (abstract).

The prior art vaccine composition and methods appear to be the same or similar to that claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine composition and methods with the vaccine composition and methods of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed vaccine composition and methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

April 1, 2003